# Complete Summary

## GUIDELINE TITLE

HIV post-exposure prophylaxis for children beyond the perinatal period.

## BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV post-exposure prophylaxis for children beyond the perinatal period. New York (NY): New York State Department of Health; 2002 Mar. 26 p. [36 references]

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Hepatitis B virus infection
- Hepatitis C virus infection
- Sexually transmitted diseases
- Sexual assault

### GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

### CLINICAL SPECIALTY

Allergy and Immunology
Family Practice

Infectious Diseases
Pediatrics

## INTENDED USERS

Health Care Providers
Physician Assistants
Physicians
Public Health Departments

## GUIDELINE OBJECTIVE(S)

To help medical providers identify and treat pediatric patients with potential human immunodeficiency virus (HIV) exposures

## TARGET POPULATION

Children beyond the perinatal period with potential human immunodeficiency virus (HIV) exposures

## INTERVENTIONS AND PRACTICES CONSIDERED

### Initial Evaluation

1. Ascertaining whether exposure is associated with potential risk of human immunodeficiency virus (HIV) infection
2. Notification of parent or guardian
3. Referral of child to medical facility or emergency room for further evaluation
4. Cleansing of wound or irrigation of mouth and eyes, as appropriate
5. Assessment of HIV status, without violation of right to confidentiality
6. Assessment of risk for other pathogen
7. Blood count (CBC)
8. Liver function tests (LFTs)
9. HIV enzyme-linked immunosorbent assay (ELISA)

### Treatment/Management

1. Discussing benefits and risk of post-exposure prophylaxis with family and child
2. Post-exposure prophylaxis for HIV: zidovudine (Retrovir, AZT), lamivudine (Epivir, 3TC), nelfinavir (Viracept)
3. Clinical follow-ups to include complete blood count, liver function tests, and HIV ELISA
4. Assessment of psychosocial status and obtaining referrals if needed
5. Post-exposure prophylaxis following exposure to other infectious agents:
    - Administration of hepatitis B vaccine series
    - Administration of hepatitis B immune globulin
    - Determination of serostatus if child has been previously vaccinated
    - Determination of hepatitis C serologic status in cases of needlestick exposure

- Assessment of tetanus vaccination status in cases of needlestick exposure and administration of tetanus toxoids and tetanus immune globulin if vaccination status is not up-to-date
- Cleansing of bite wounds and administration of antibiotics, as appropriate

6. Obtaining consent for treatment

Evaluation and Management of Sexual Assault

1. Inclusion of a Sexual Assault Forensic Examiner (SAFE) trained in pediatric examinations on evaluation team
2. Availability of appropriate resources to address medical, psychosocial, and legal issues
3. Assessment of child for risk of sexually transmitted disease, with laboratory evaluation and antimicrobial prophylaxis as appropriate

Prevention

1. Home and school instruction about avoiding potentially risky exposures
2. Age-appropriate discussions between physician and child concerning reduction of risky behaviors

### MAJOR OUTCOMES CONSIDERED

Human immunodeficiency virus (HIV) transmission rate after exposure to HIV and after prophylaxis

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person 3 to 4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

#### Assessment of Exposure and Need for Referral to a Medical Facility

Following an exposure, the health care provider should ascertain whether the exposure is associated with a potential risk of human immunodeficiency virus (HIV) transmission and whether it has occurred within the previous 36 hours.

Potential exposures that may pose a risk of HIV transmission include:

- Break in the skin by an object that is visibly contaminated with blood or that has been in a blood vessel
- Bite wound that results in bleeding in the person bitten or the person biting
- Splash of blood, visibly bloody body fluids, or other potentially infectious body fluid to a mucosal surface
- Exposure of non-intact skin to blood or bloody body fluid
- Exposure of mucous membranes or of non-intact skin to semen or blood during sexual exposure

If a potential risk exposure has taken place, the provider should:

- Notify the parent or legal guardian.
- Refer the child to a medical facility or emergency room for immediate further evaluation of the risk of exposure and the need for post-exposure prophylaxis (PEP).
- If appropriate, the provider should clean the wound with warm water and soap or irrigate the mouth and eyes copiously with tap water.
- Try to assess the HIV status of the source patient without violating the source patient's right to confidentiality.
- Assess the risk for exposure to other pathogens, including hepatitis B virus (HBV) and hepatitis C virus (HCV), tetanus, sexually transmitted diseases, and bacterial infections, and should treat as necessary

#### Initiation of Post-Exposure Prophylaxis

Key issues about PEP should be discussed with the family and child as soon as possible. These include:

- Potential benefits of HIV PEP
- Potential toxicities associated with medications
- Potential side effects associated with medications
- Instructions on how and when to give the medications
- Importance of adherence to the medication regimen
- Nature and duration of medication regimen and monitoring schedule

A commonly used combination for PEP is zidovudine, lamivudine, and nelfinavir (dosing recommendations are provided in Table 3 in the original guideline document). However, if the source patient is known to be HIV-infected, the provider should inquire about previous antiretroviral (ARV) therapy, level of viral

suppression, and resistance profile. This information may guide the provider, in consultation with an HIV Specialist, to choose a regimen that more effectively suppresses viral replication in the exposed child.

The prophylactic medication regimen should be started promptly and should be continued for 28 days.

Medications should be made available to the patient in sufficient supply to complete a course of prophylaxis.

Before starting therapy, the provider should obtain complete blood count (CBC), liver function tests (LFTs), and an HIV enzyme-linked immunosorbent assay (ELISA).

Initial follow-up of the exposed child should occur within 2 to 3 days to review medication regimen, assess psychosocial status of child and family, and arrange appropriate referrals (e.g., psychosocial counseling after sexual assault).

Arrangements should be made for clinical follow-up at 2 weeks and 4 weeks; CBC and LFTs should be repeated at 2 (optional) and 4 weeks.

An HIV ELISA should be repeated at 4, 12, and 26 weeks after exposure.

Post-Exposure Prophylaxis Following Exposures to Other Infectious Agents

If the exposed child is not fully immunized against hepatitis B, the child should receive hepatitis B immune globulin and should begin or continue the hepatitis B vaccine series. If the child has been previously vaccinated against hepatitis B, the child's serostatus should be determined. If the child has serologic immunity to hepatitis B, no further action is necessary; if the child does not have serologic immunity, revaccination should be initiated.

The baseline hepatitis C serologic status of the exposed child should be determined in cases of needlestick exposure. There are currently no recommendations for prophylaxis for hepatitis C virus (HCV). Repeat testing for hepatitis C serologic status should be performed at 26 weeks. Repeat testing for hepatitis C serologic status or polymerase chain reaction (PCR) for HCV may be considered at 2 to 4 weeks after exposure.

The tetanus vaccination status of the victim should be assessed in cases of needlestick exposure or bite wound. Tetanus toxoids and tetanus immune globulin should be given if the vaccination status is not up-to-date.

Bite wounds should be cleansed. Antibiotics should be initiated in severe wounds, deep puncture wounds, and wounds to the face, genitals, or extremities.

Evaluation of Sexual Assault

Evaluation of and treatment for sexual assault should be managed by a multidisciplinary team that is experienced in the care of children or adolescents who have been sexually assaulted.

A Sexual Assault Forensic Examiner (SAFE) who is trained to perform pediatric examinations should be included on the team whenever possible to assist in the medical examination, coordination of care, and discussions about treatment regimen (see Appendix 19-B in the original guideline document).

Children and adolescents who are sexually assaulted should be managed in an emergency room or other setting where appropriate resources are available to address the medical, psychosocial, and legal issues of such an offense.

Children who are sexually assaulted should be assessed for the risk of acquiring other sexually transmitted diseases, including gonorrhea, syphilis, chlamydia, hepatitis B, herpes simplex virus, human papillomavirus, bacterial vaginosis, and Trichomonas. Laboratory evaluation and possible antimicrobial prophylaxis should be considered depending on the nature of the assault.

Consent for Treatment

When parental or legal guardian consent cannot be obtained to initiate HIV PEP in a minor, the treatment may be initiated. Parental/legal guardian consent is strongly recommended to continue PEP beyond the first few hours/days. Emancipated minors, married minors, and minors who are parents may provide consent for medical care and treatment.

Prevention

Children should be instructed in school and at home about potentially risky exposures and how to avoid them. The physician should discuss reduction of potentially risky behaviors with all children in a manner that is appropriate to their age and developmental stage as a routine component of pediatric care.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not stated.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- An observational study from New York State described a transmission rate of 6.1% when zidovudine (ZDV) was initiated in the prenatal period, 10.0%

when initiated in labor, and 9.3% when initiated within 48 hours after birth; most prophylaxis in the latter study was initiated within 12 hours after birth. The transmission rate was 26.6% with no ZDV prophylaxis. This observational study provides additional evidence of the efficacy of post-exposure prophylaxis (PEP).
- A Centers for Disease Control and Prevention (CDC) retrospective case control study of human immunodeficiency virus (HIV) PEP with ZDV in health care workers demonstrated a 79% reduction in transmission (95% confidence interval [CI], 43-94%) after percutaneous exposure to HIV. The risk of HIV transmission was greater when the health care worker was exposed to a larger volume of blood.

### POTENTIAL HARMS

Potential toxicities and side effects associated with medication:

- Zidovudine: bone marrow suppression, anemia, neutropenia, thrombocytopenia, nausea, myalgia, headaches, hepatotoxicity
- Lamivudine: pancreatitis, peripheral neuropathy
- Nelfinavir: diarrhea, nausea, vomiting, headache

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- These guidelines are based on best practice evidence and constitute the opinion of the New York State Department of Health (NYSDOH) Committee for the Care of Children and Adolescents With Human Immunodeficiency Virus (HIV) Infection. There are no clinical trials in the pediatric age group to guide decision-making in the management of pediatric post-exposure prophylaxis (PEP) for HIV, and consultation with a pediatric HIV Specialist is recommended.
- Although in general the NYSDOH recommends a three-drug regimen for PEP, the Committee did not reach consensus. Some believed that the issues of toxicity and poorer adherence with a three-drug regimen warranted use of a two-drug regimen in some cases. Others believed that a three-drug regimen was always preferable. More recently available formulations of medications include combination pills and once daily dosing that are more convenient. These have not been extensively studied in the context of PEP but have been proven effective in the treatment of HIV infection.
- Recent information distributed by the Roxane Laboratories, the manufacturer of nevirapine, warns of severe, life-threatening cases of hepatotoxicity and some deaths in association with nevirapine therapy in adults. Serious hepatotoxicity (including liver failure) also was reported in patients receiving nevirapine as part of a PEP regimen. For this reason, the Committee does not recommend the routine use of nevirapine in PEP regimens. If the clinician chooses to use nevirapine in a combination regimen, careful monitoring of liver function is indicated.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening, or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York´s HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience
- Define target audience (providers, consumers, support service providers)
    - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)
- Define implementation methods
    - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes
    - What steps need to be taken to make these activities happen?
    - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?
    - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
    - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress
    - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate
    - Did the processes and strategies work? Were the guidelines implemented?
    - What could be improved in future endeavors?

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

## IOM DOMAIN

Effectiveness
Timeliness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV post-exposure prophylaxis for children beyond the perinatal period. New York (NY): New York State Department of Health; 2002 Mar. 26 p. [36 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2002 Mar

### GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

### SOURCE(S) OF FUNDING

New York State Department of Health

### GUIDELINE COMMITTEE

Not stated

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

### GUIDELINE STATUS

This is the current release of the guideline.

### GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- HIV post-exposure prophylaxis for children beyond the perinatal period. Tables and recommendations. New York (NY): New York State Department of Health; 2003 Mar. 17 p.
- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p.

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was prepared by ECRI on January 21, 2004.

## COPYRIGHT STATEMENT



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